Validity Testing Information Part I

Laboratory Name: Quest Diagnostics #0068
Address: 7600 Tyrone Ave. Van Nuys, CA 91405

Responsible Person: Louis Jambor (Printed Name)

I certify that the answers and information provided are true and correct as of this date. Any false, fictitious, or fraudulent answers or information provided may violate Federal Law and could subject me to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31 U.S.C. 3801-812).

Signature, Responsible Person

10-5-00
Date

Louis C. Tamber
Printed Name, Responsible Person

Validity Testing Information Part II

Conduct an audit of all DOT regulated specimens from the date your laboratory started validity testing. Summarize your findings in an Excel spread sheet in both hard copy and electronic format. Provide the following information in a separate column of the spreadsheet/audit for *each* DOT regulated specimen that was reported either adulterated or substituted:

- **Specimen ID number**
- **Laboratory Accession Number**
- **Date of receipt**
- **Date reported**
- **Reported result (i.e., adulterated or substituted)**
- **Quantitative test result (e.g., actual creatinine concentration and specific gravity reading; actual pH reading; adulterant identity and its concentration if applicable)**

Note: Retain a copy of this information to ensure that you would be able to retrieve additional data.

I certify that the answers and information provided are true and correct as of this date. Any false, fictitious, or fraudulent answers or information provided may violate Federal Law and could subject me to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31 U.S.C. 3801-812).

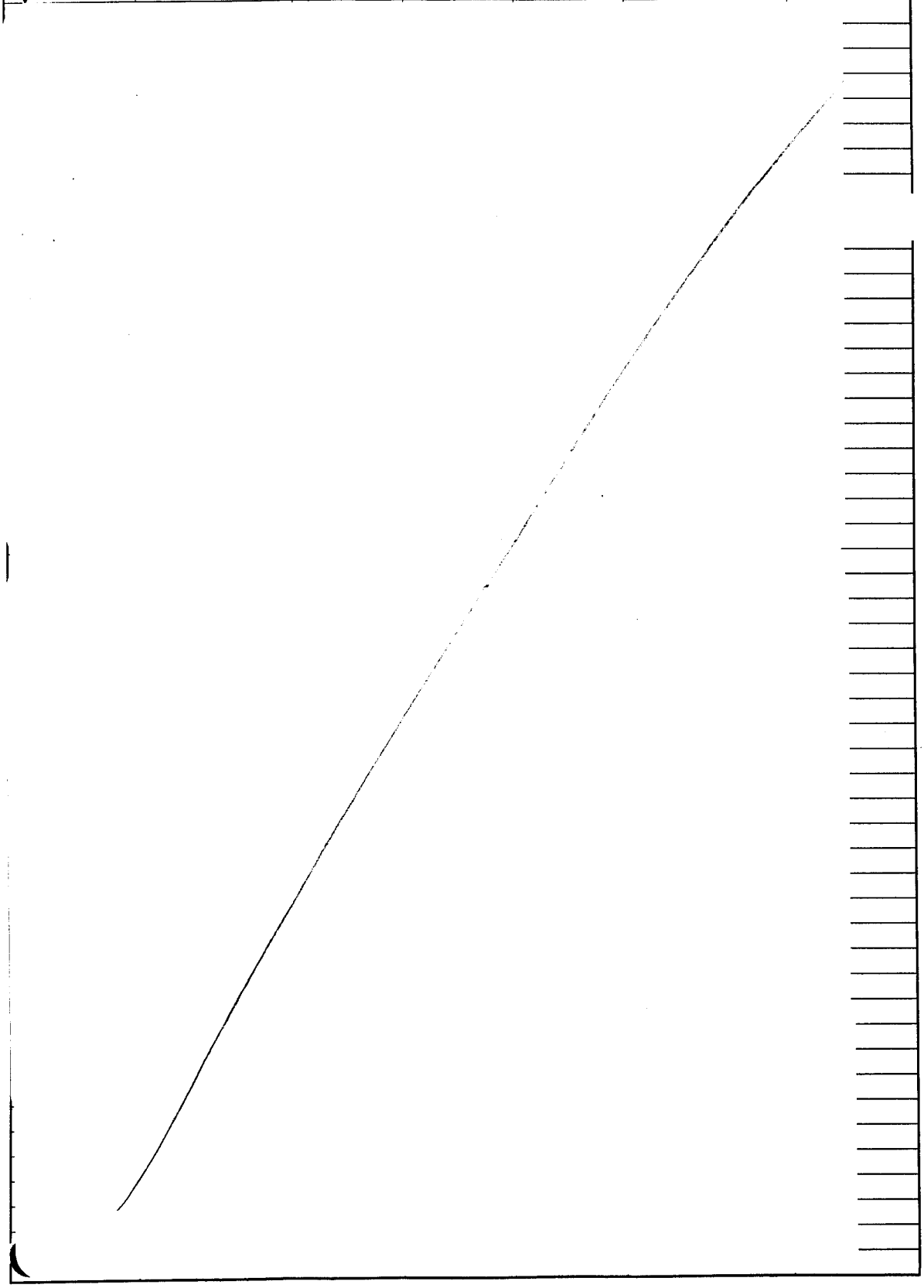
Signature, Responsible Person

10/16/00
Date

Louis G. JAMBOR
Printed Name, Responsible Person

Audit

RCV DATE	REP DATE	Lab	ACN	Req No	PYRID(mg/mL)	BLEACH



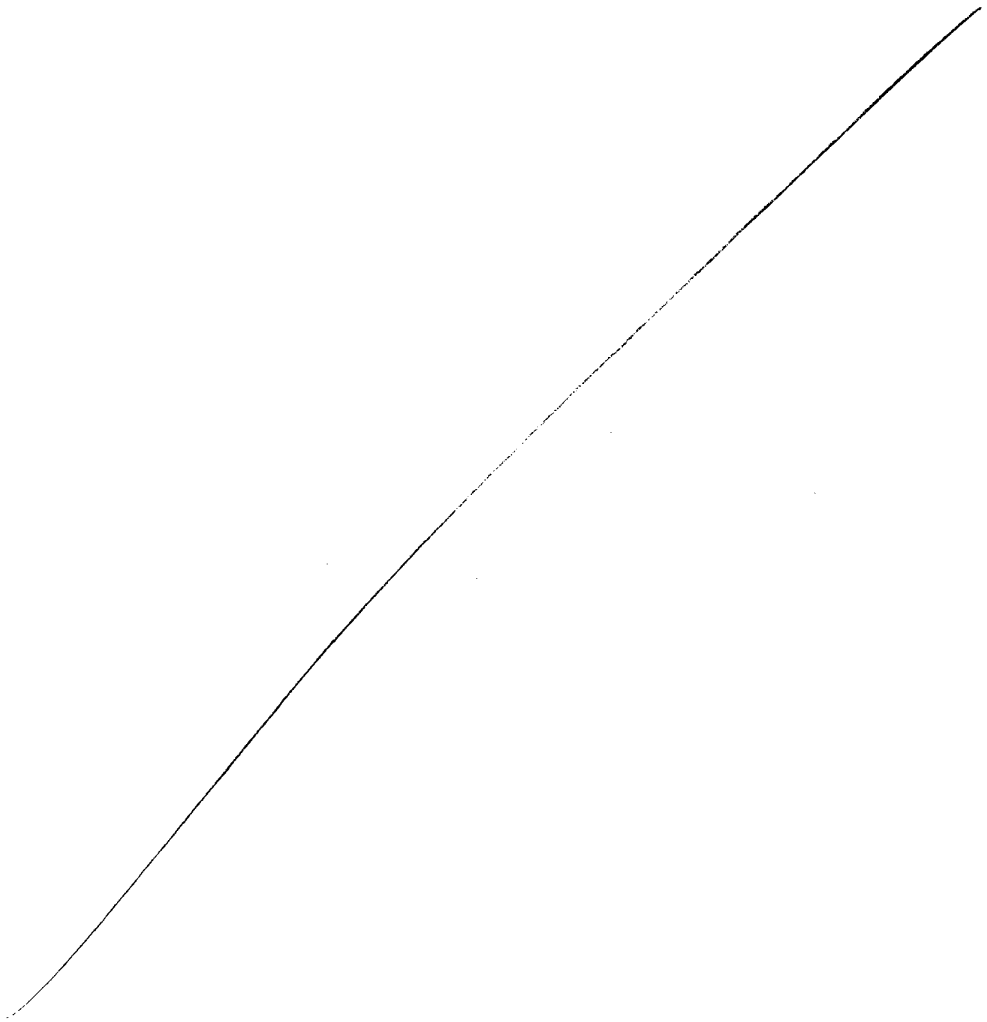
Audit

RCV DATE	REP DATE	Lab	ACN	Req No	PYRID(mg/mL)	BLEACH

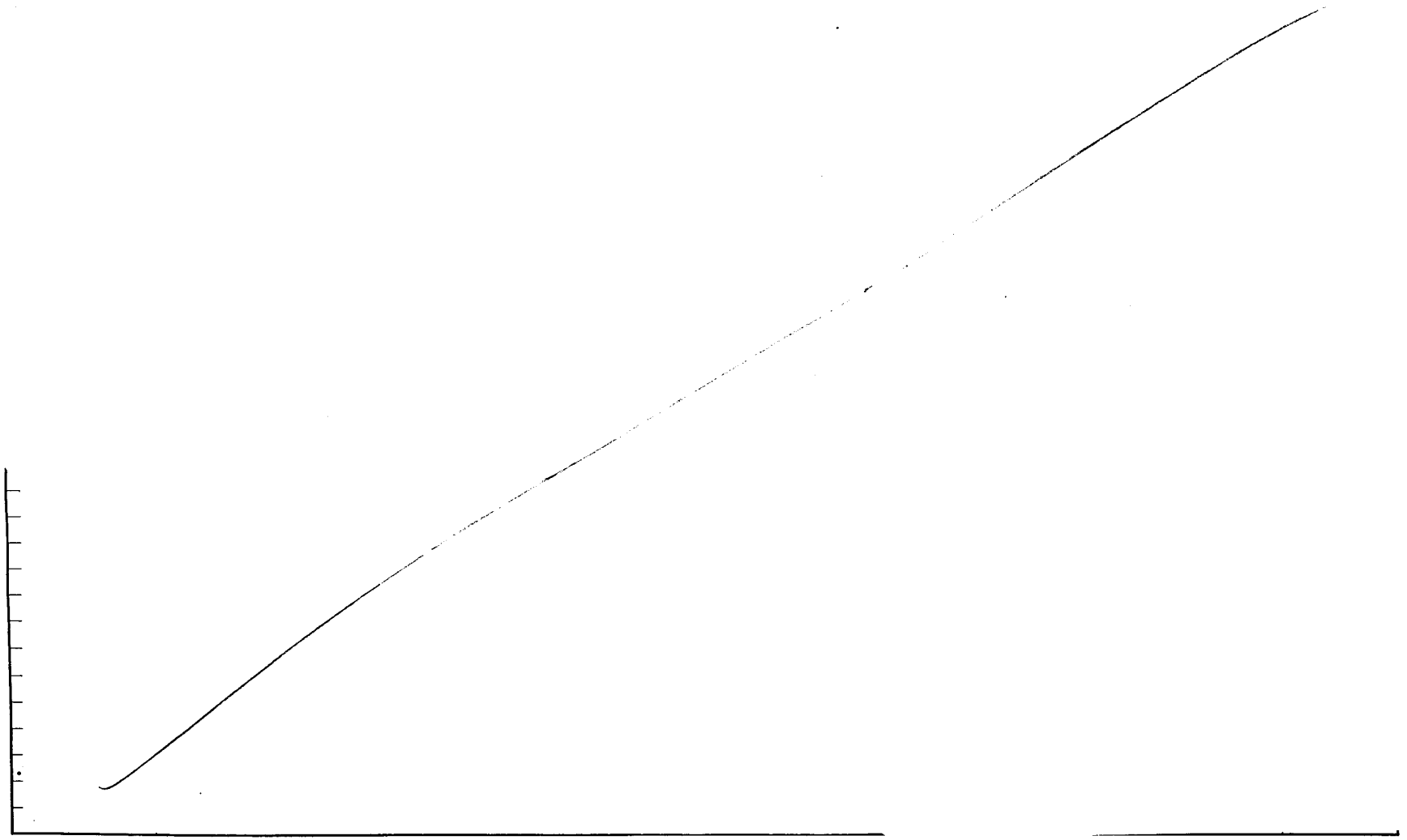
Audit

RCV DATE	REP DATE	Lab	ACN	Req No	PYRID(mg/mL)	BLEACH

RCV DATE	REP DATE	Lab	ACN	Req No	NIT	CREAQ	SPGQ	pH	GLUTAR	PYRID(mg/mL)	BLEA



RCV DATE	REP DATE	Lab	ACN	Req No	NIT	CREAQ	SPGQ	pH	GLUTAR	PYRID(mg/mL)	BLEA



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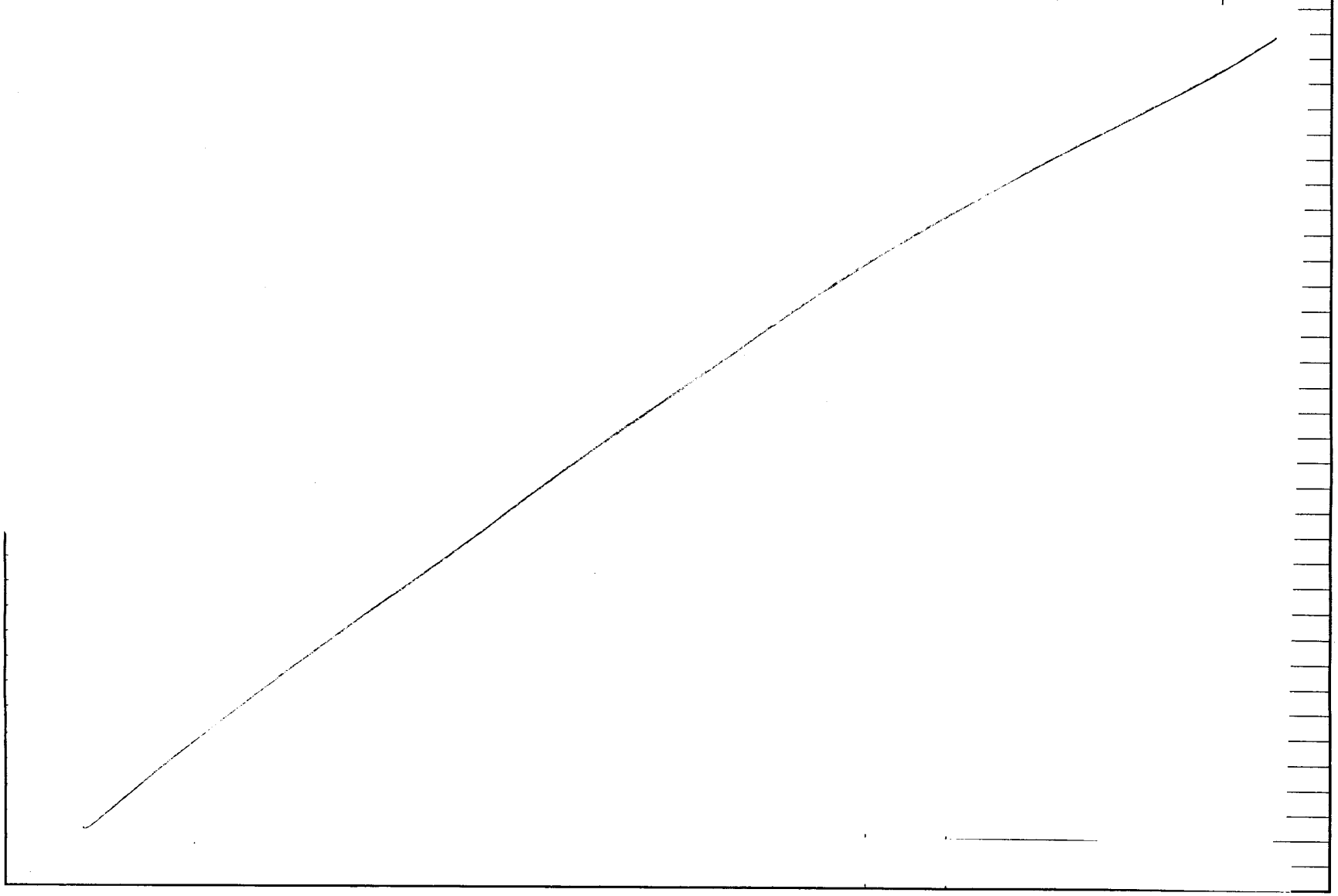

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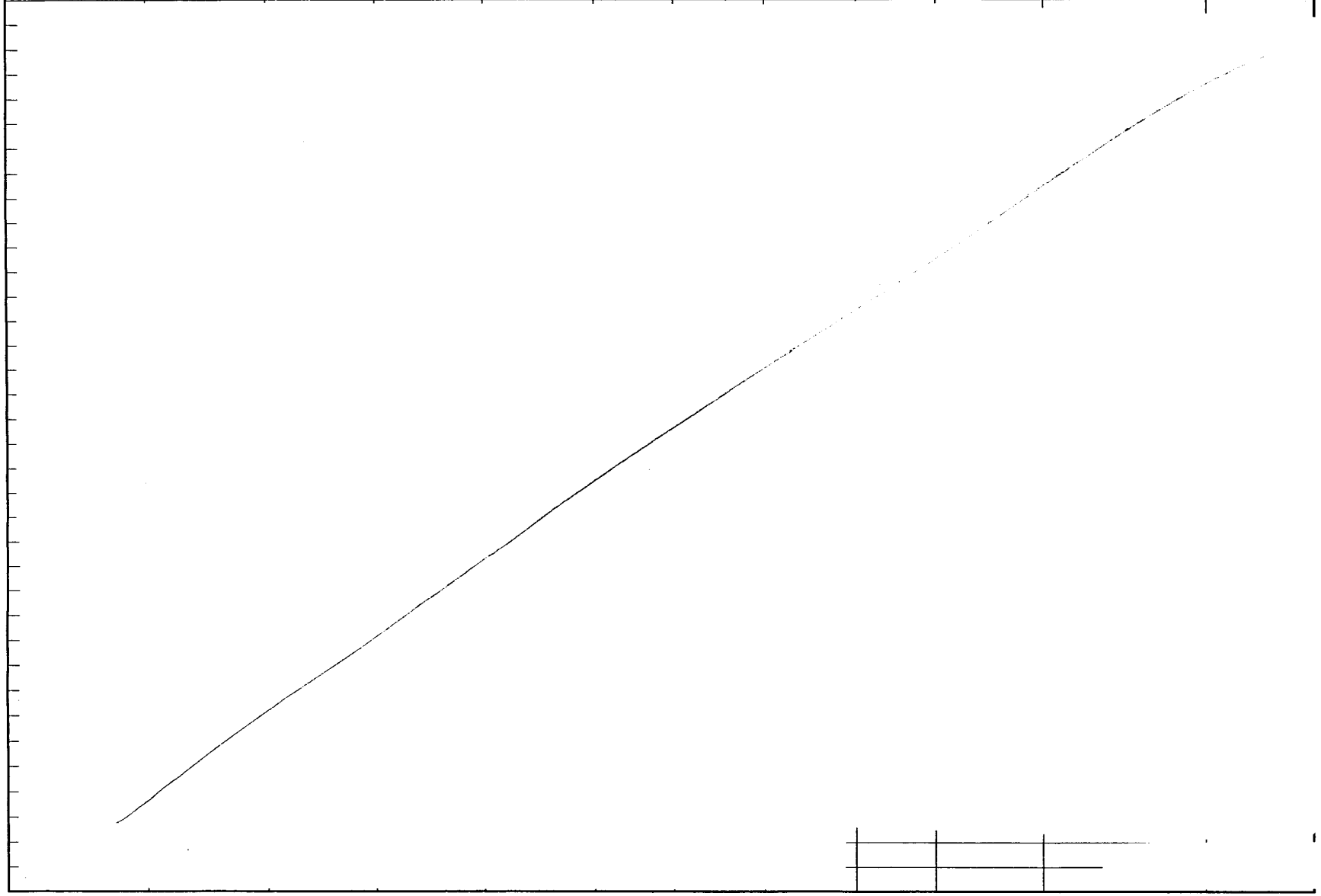

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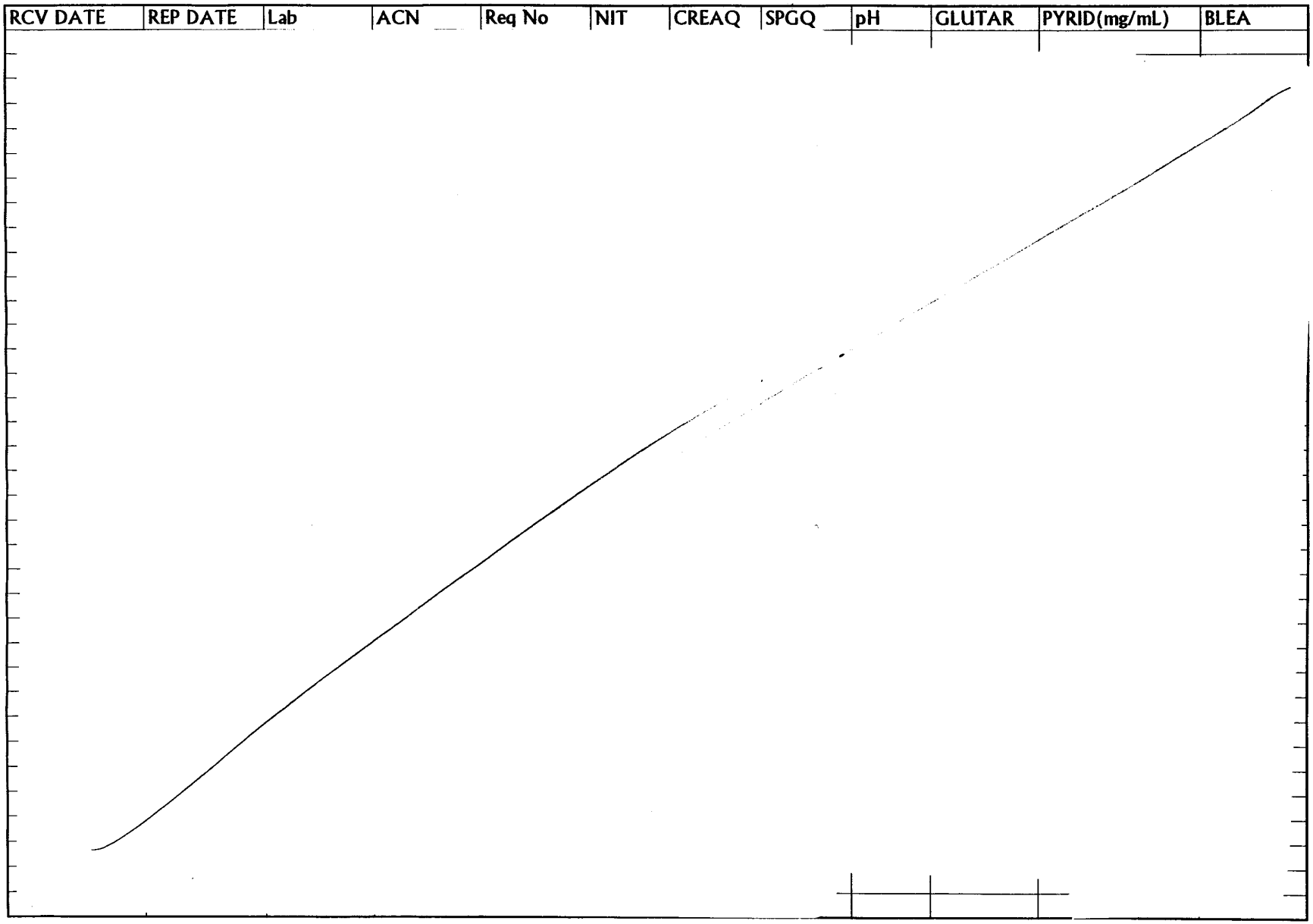

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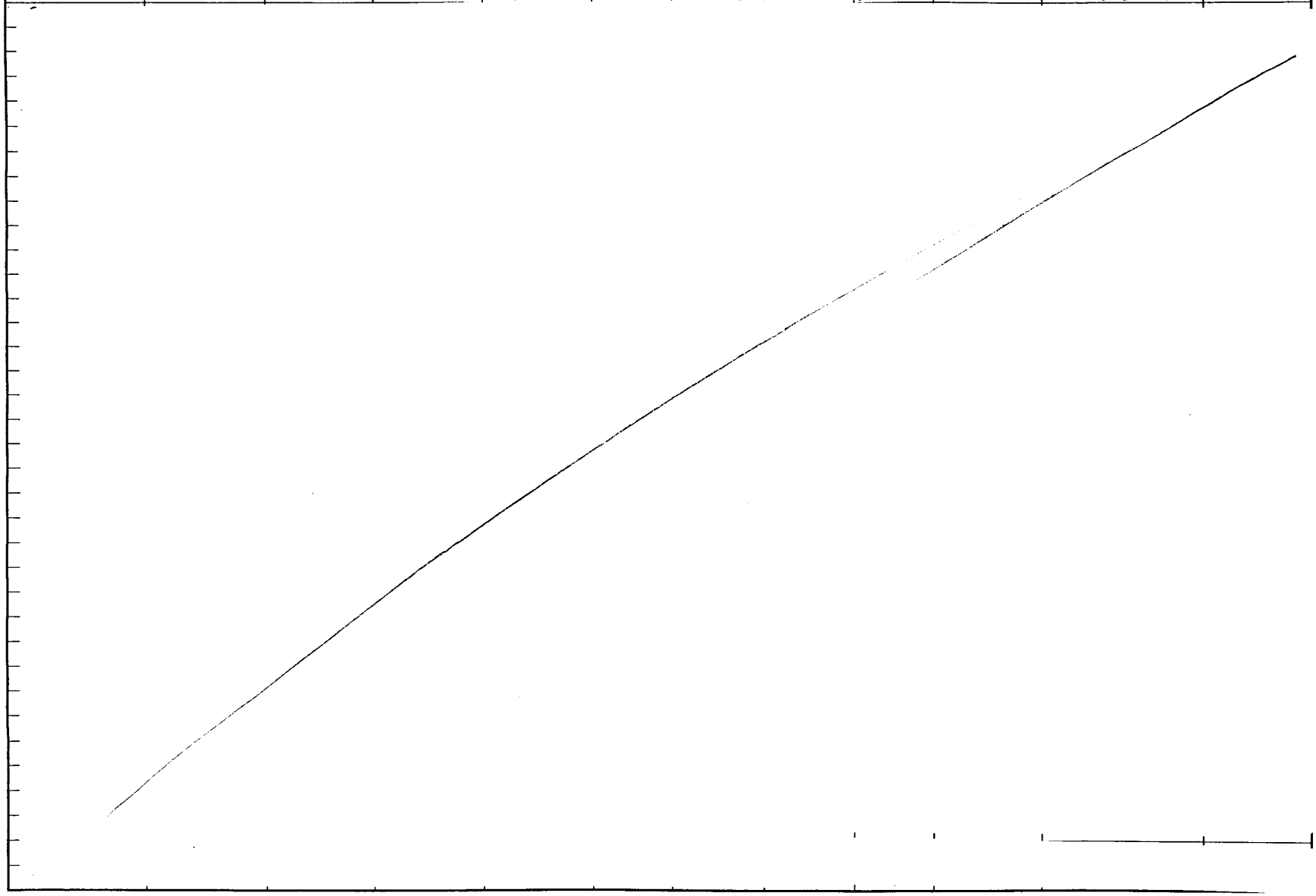

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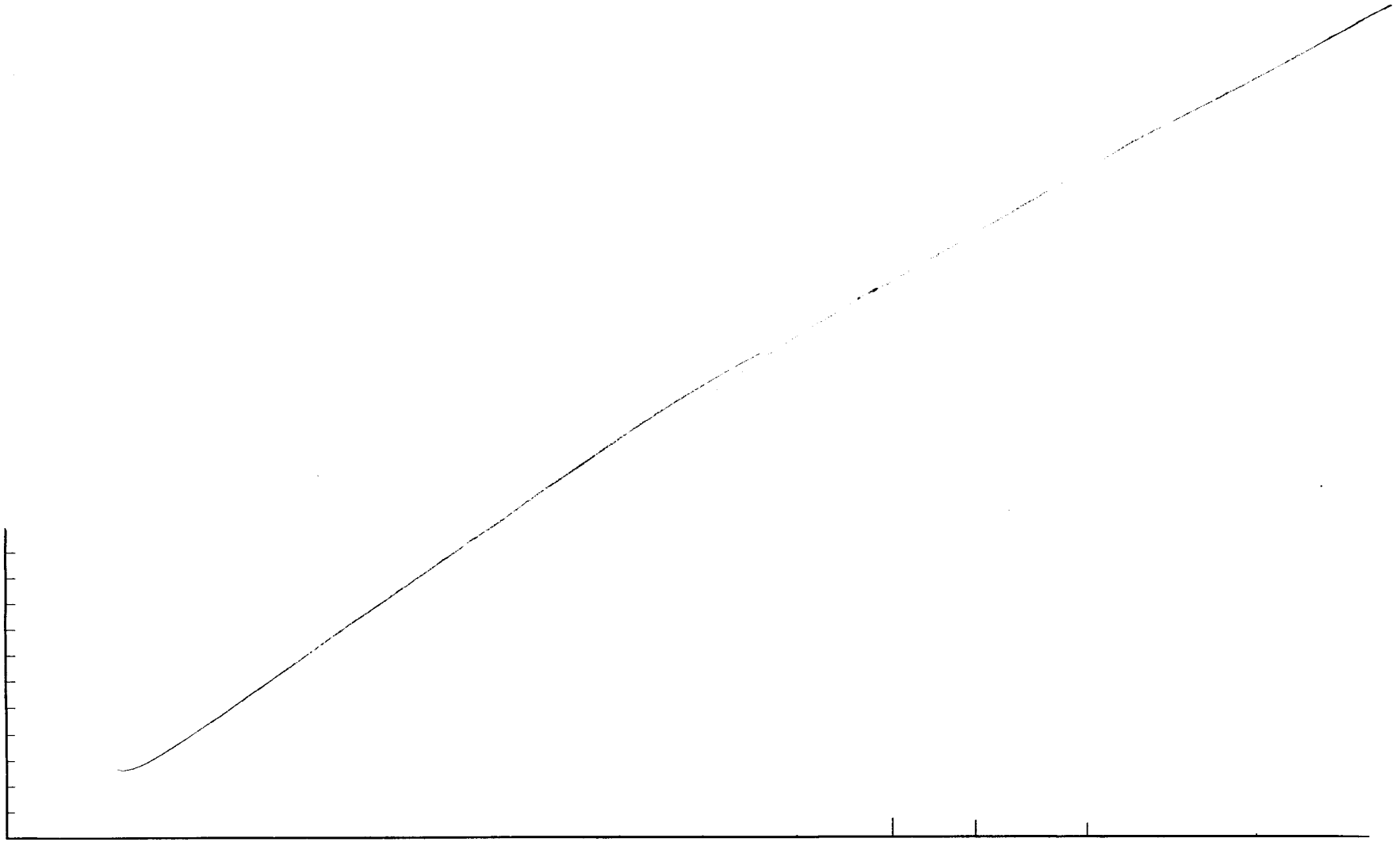


RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 18, 2000

0068
Dr. Louis Jambor
Quest Diagnostics Incorporated
7600 Tyrone Avenue
Van Nuys, CA 91405

Dear Dr. Jambor:

The enclosed critique was developed from the inspection report associated with the November 08, 2000 specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures were not in compliance with program guidance issued in Program Document 035 (September 28, 1998) and Program Document 037 (July 28, 1999). The laboratory must submit information to address the following issues raised:

3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
Telephone 919 541-6709 • Fax 919 541-7042

The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issues listed in this correspondence. The laboratory must also review the enclosed critique and take all necessary corrective actions. In responding to these issues, please organize the material in your document in accordance with the sections and item numbers as listed in this correspondence. All corrective actions must be implemented within 30 days receipt of this correspondence and will be reviewed at the next inspection. ***Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens.***

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson

Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/svt068

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0068
Document No. Final

Laboratory: Quest Diagnostics Incorporated

Location: Van Nuys, CA

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 8 November 2000

A review of the National Laboratory Certification Program (NLCP) consensus inspection report has been completed. Issues identified during the inspection are described on the following pages. Evidence that appropriate remedial action has been taken is required for continued certification.

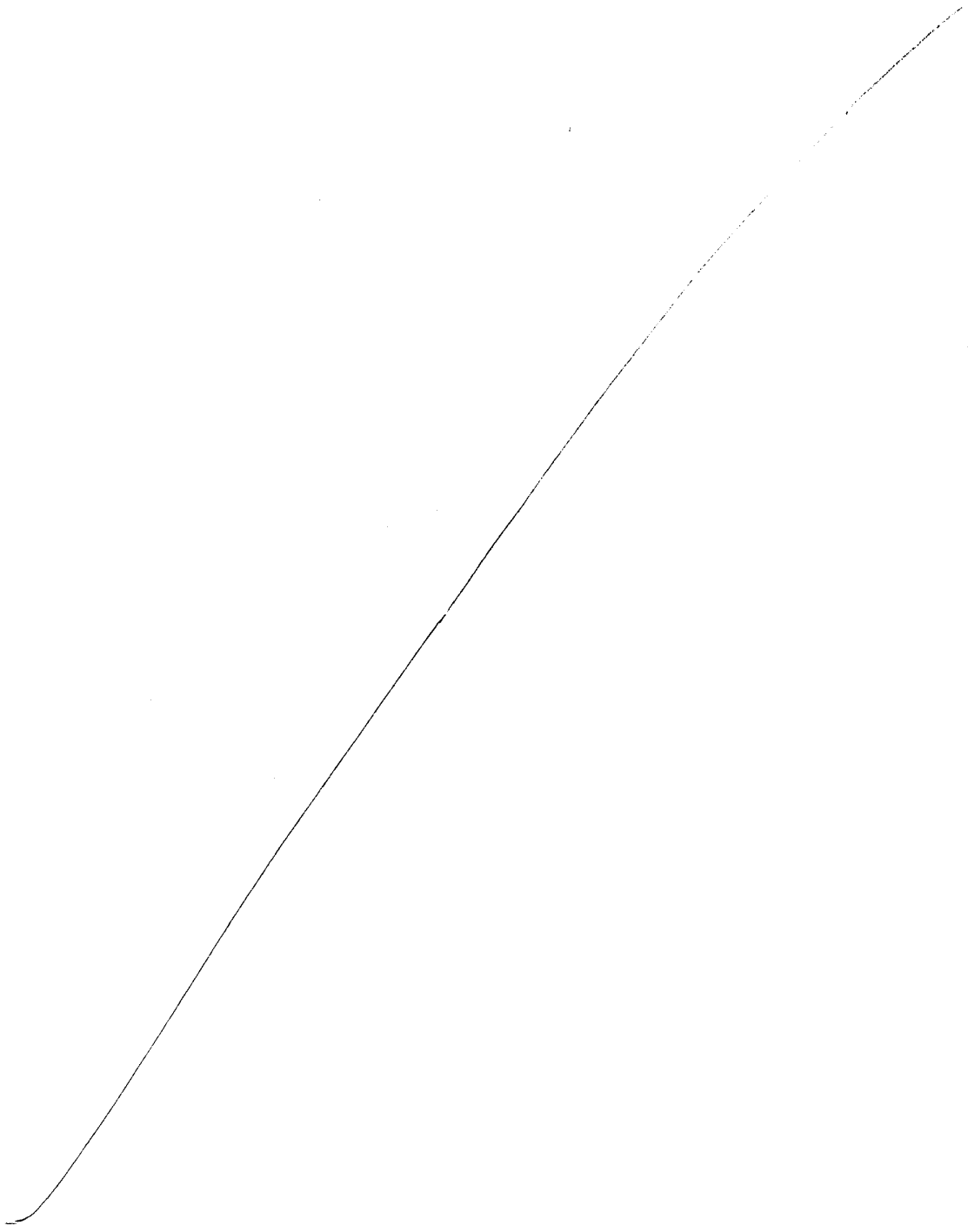
The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

Section E. Standard Operating Procedures - Procedures Manual

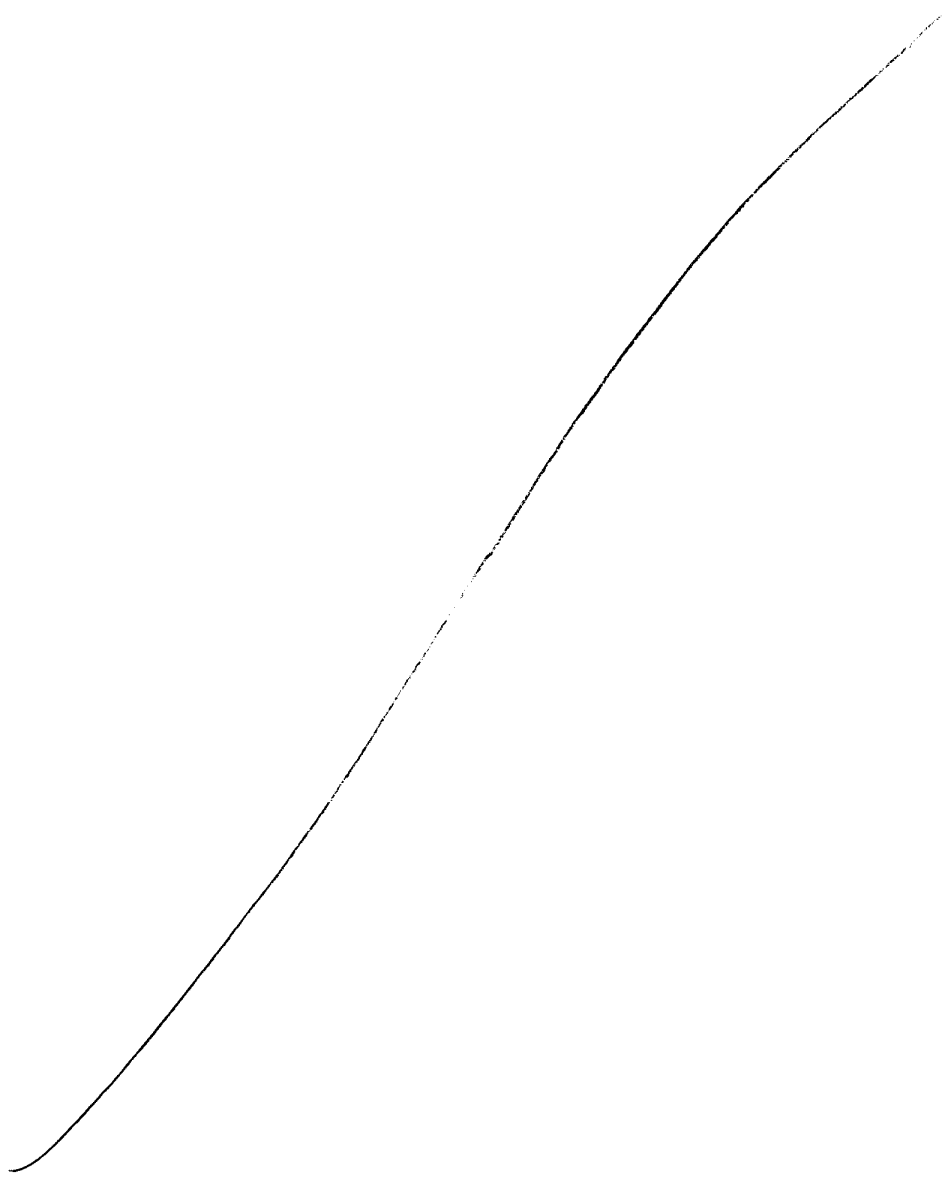
Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control and Quality Assurance

Section I. Specimen Validity Tests



Section K. Records Audit



Section L. Certification and Reporting

Quest Diagnostics Incorporated

7600 Tyrone Avenue
Van Nuys, CA 91405-1449

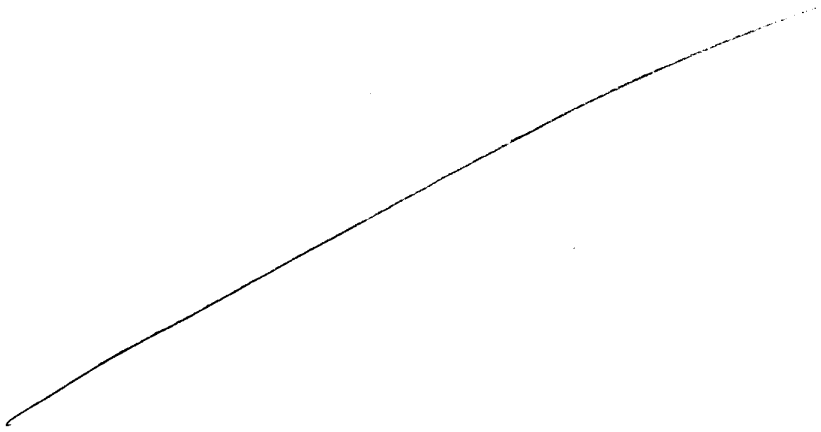
January 19, 2001

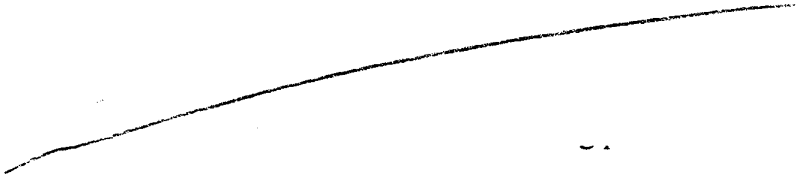
Deborah Denson
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

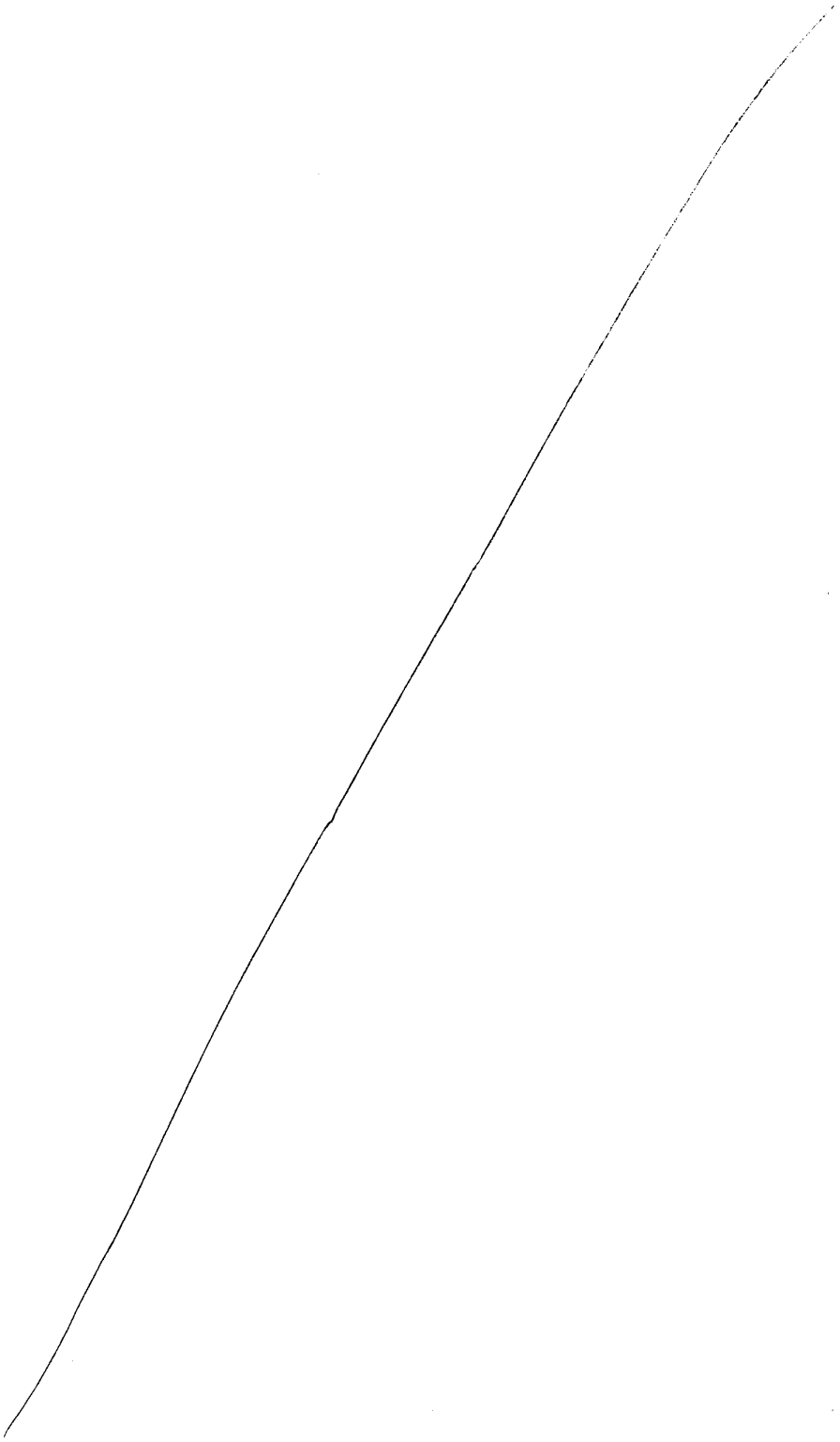
Dear Ms. Denson:

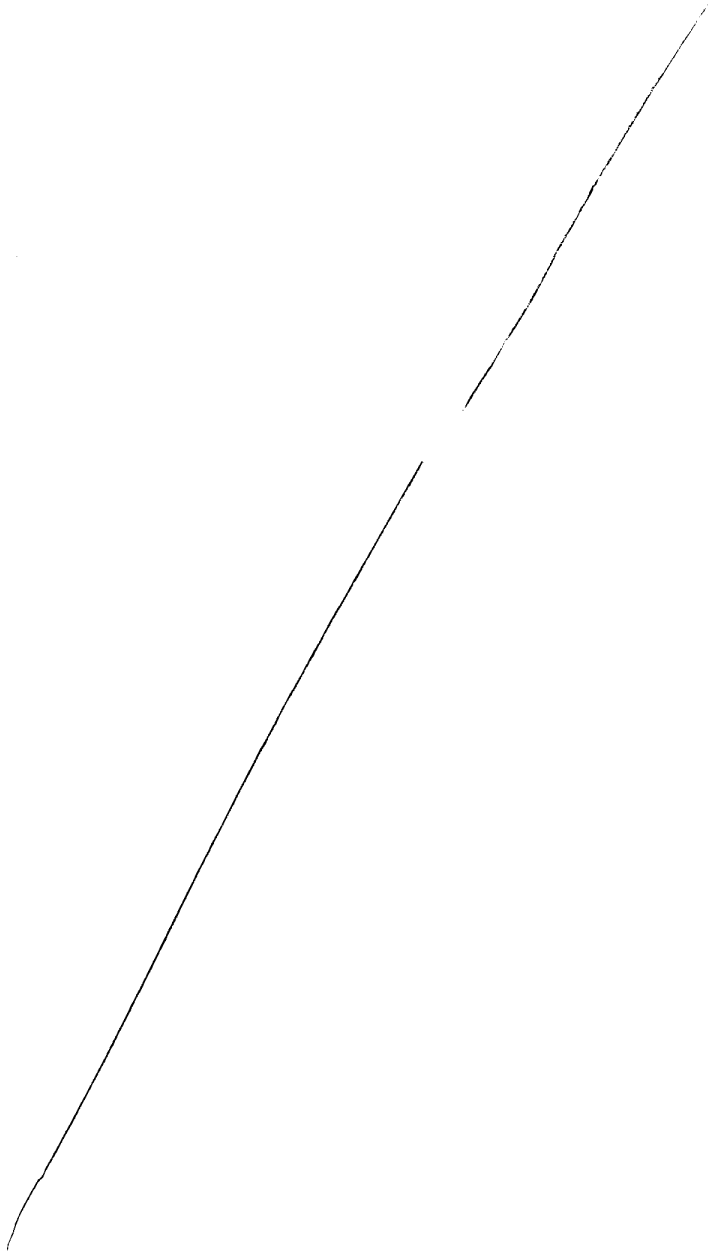
The following is our response to the critique of the SVT inspection of Quest Diagnostics in Van Nuys, California (Lab # 0068) that took place on November 8-10, 2000.

[7







Please contact me if you have any questions regarding this response.

Sincerely,

Louis G. Jambor, Ph.D.
Forensic Testing Director
(800) 877-2520

RESEARCH TRIANGLE INSTITUTE

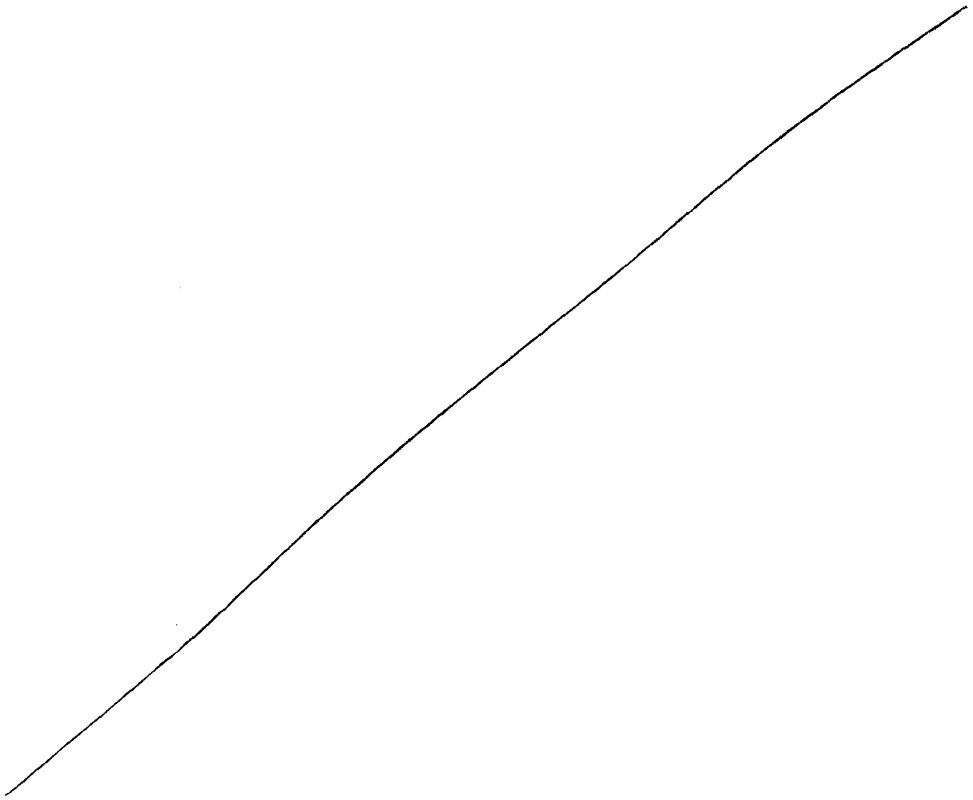
National Laboratory Certification Program

February 2, 2001

0068
Dr. Louis Jambor
Quest Diagnostics Incorporated
7600 Tyrone Avenue
Van Nuys, CA 91405

Dear Dr. Jambor:

We have reviewed the material provided in your correspondence of January 19, 2001 submitted in response to issues raised during the November 08, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of December 18, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions have been taken to address the issues raised. The following is a review of the material submitted:



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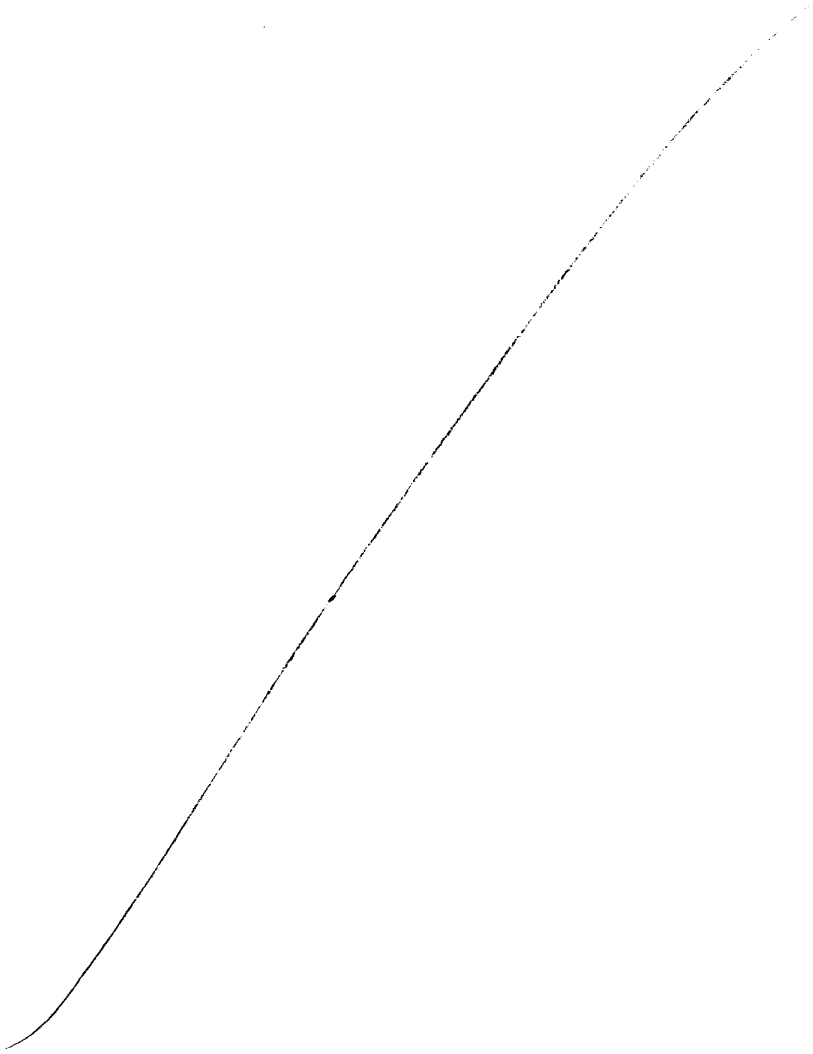
Telephone 919 541-6709 • Fax 919 541-7042



Based upon our review of the material submitted, it appears that the laboratory is taking steps to ensure that its specimen validity testing procedures are in compliance with program guidance. All corrective actions must be implemented within 30 days of the receipt of this correspondence and will be reviewed during the next inspection.

Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens.

If you have any questions or if we can be of further assistance, please call me at (919) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/SVT068